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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,000	11/03/2003	Daria Jerome	CONLINCO-08440	2982

7590 10/20/2004
MEDLEN & CARROLL, LLP
Suite 350
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San Francisco, CA 94105

EXAMINER

CARR, DEBORAH D

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,000

Applicant(s)

JEROME ET AL.

Examiner

Deborah D Carr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 6-12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-12 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 4-5, filed 23 August 2004, with respect to the rejection(s) of claim(s) 6-12 & 14-17 under 35 USC §112 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 USC § 112, first paragraph.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6-11 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for elevating CD-4 and CD-8 cell counts in animals, does not reasonably provide enablement for broadly claiming the elevation of "all" white blood cell counts in a mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

At most, the instant specification might be considered enabled for elevating CD-4 and CD-8 cell counts in animals (see page 13, lines 5-19), but there does not seem to be any enablement for broadly claiming the elevation of "all" white blood cell counts in a

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mammal. As disclosed in US-5,674,901, CLA has been shown to be affective in maintaining or elevating CD-4 and CD-8 cell levels of animals, including humans. As shown in col.6, lines 62-67, to col. 7, lines 1, the animals referred to are those that ingest animal feed (i.e. poultry feed). However, there is no evidence that these compounds (CLA) can treat "all" mammal therefore one would not extrapolate that the instant compounds would elevate CD-4 and CD-8 cell counts in all mammals.

4. Claims 12, 14-17 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In reviewing the specification, the instantly claimed invention has not been exemplified but appears to be an observation in the discussion of US. Pat. 5,585,400 (see page 8, lines 31-35).

Other than the information supra that was incorporated by reference, applicants have not described in the specification the subject matter of the claimed invention.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6-11 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious Cook et al. (US-5,674,901).

Cook et al. teaches CLA can be used to elevate or increase CD-4 and CD-8 cell populations in animals. The claims differ in that a ratio of 1.2:1 to 3:1 is given for t10, c12 octadecadienoic acid and t9, c11 octadecadienoic acid respectfully.

However, US'901 teaches that a mixture containing effective amounts of t10, c12 octadecadienoic acid and t9, c11 octadecadienoic acid are given to elevate or increase CD-4 and CD-8 cell populations in animals.

Although ratios are not specifically taught, it is clearly stated in col. 8 that it would be obvious and readily apparent to those skilled in the art to modify or make changes without departing from the spirit and scope of the invention. The mere use of the word "preferable" in the specification is not controlling evidence of criticality for the purpose of establishing unobviousness. In re Rauch, 390 F.2d 760, 156 U.S.P.Q. 502 (C.C.P.A. 1968). Hays v. Reynolds, 145 U.S.P.Q. 665 (D.C.D.C. 1965).

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8. Claims 12, 14-17 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious Cook et al. (US-5,585,400).

Cook et al. teaches CLA can be used to treat type I or IgE hypersensitivity in animals. The claims differ in that a ratio of 1.2:1 to 3:1 is given for t10, c12 octadecadienoic acid and t9, c11 octadecadienoic acid respectfully.

However, US'400 teaches that a mixture containing effective amounts of t10, c12 octadecadienoic acid and t9, c11 octadecadienoic acid are given to treat type I or IgE hypersensitivity in animals.

Although ratios are not specifically taught, it is clearly stated in col. 6 that it would be obvious and readily apparent to those skilled in the art to modify or make changes without departing from the spirit and scope of the invention. The mere use of the word "preferable" in the specification is not controlling evidence of criticality for the purpose of establishing unobviousness. In re Rauch, 390 F.2d 760, 156 U.S.P.Q. 502 (C.C.P.A. 1968). Hays v. Reynolds, 145 U.S.P.Q. 665 (D.C.D.C. 1965).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D Carr whose telephone number is 571-272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Deborah D. Carr". The signature is fluid and cursive, with the first name "Deborah" and last name "Carr" being clearly distinguishable.

DEBORAH D. CARR
PRIMARY EXAMINER

ddc